REMARKS

I. Preliminary Remarks

A Request for Continued Examination (RCE) was filed on June 28, 2007 under 37 CFR 1.114. The finality of the office action on December 21, 2006 has been withdrawn, and Applicant's submission of June 28, 2007 has been entered.

After entry of this paper, Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 are under consideration. Claims 12-19, and 32-75 are withdrawn. Claims 6, 24, 26, 78, and 83 are canceled. Withdrawn and canceled claims are withdrawn without prejudice in an effort to favorably advance prosecution of the present application. Applicant reserves the right to pursue the subject matter of the withdrawn or canceled claims in a continuation application, or to have the withdrawn claims rejoined in the current application.

In this response, Applicant addresses each of the rejections raised by the Examiner. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicant respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is filed with a petition for a two-month extension of time. The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Patentability Arguments

A. The Obviousness Rejection of Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts

that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

The Examiner has maintained the rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Talens, et al. (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280) or Bowland, et al., (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48) in view of Barr, et al., (Advanced Drug Delivery Reviews, 1998, Vol. 32, No. 3, pages 247-271), Pruett, et al., (Veterinary Parasitology, 1995, Vol. 58, No. 1-2, pages 143-153), and Wilson, et al., (Canadian Journal of Veterinary Research, Oct 1995, Vol. 59, No. 4, pages 299-305). Applicants respectfully traverse this rejection.

Examiner states that "the package insert for BOVI-SHIELD™ 3 indicates the vaccine comprises BVD (Type 1 and Type 2) virus." However, the package insert indicates that BOVI-SHIELD™ 3 is a freeze-dried preparation of modified live virus (MLV) strains of IBR, BVD, and PI3 viruses. It is for vaccination of healthy, nonpregnant cattle as an aid in preventing bovine viral diarrhea (Types 1 and 2) caused by bovine viral diarrhea (BVD) virus. The package insert never states that the vaccine contains both types 1 and 2. Vaccines containing BVDV type 1 can provide cross-protection against both BVDV types 1 and 2. Presented in Attachment 1 is a page taken from the Outline of Production for BOVI-SHIELD™ 3 which was filed with the US Department of Agriculture (USDA). This clearly indicates in line 1 of paragraph D that this vaccine contains only BVDV type 1. The entire Outline of production is not included herein because much of that document contains confidential information.

The same arguments apply to Bowland in regard to BOVI-SHIELD™ 4. Bowland indicates that BOVI-SHIELD™ 4 contains 4 viruses (BRSV, BVDV, IBRV, and PI-3V). It does not specify that BVDV types 1 and 2 are in the vaccine. Presented in Attachment 2 is a page taken from the Outline of Production for BOVI-SHIELD™ 4 which was filed with the USDA. This clearly indicates in line 1 of paragraph D that this vaccine contains only BVDV type 1. The entire Outline of production is not included herein because much of that document contains confidential information.

Examiner states that "Attenuated virus and killed virus are considered functionally equivalent therefore it would have been obvious to substitute one for the other. However, there is a clear difference between MLV vaccines and killed vaccines.

1. MLV can replicate in the host while killed cannot. This is the reason for dosage differences between MLV vaccines and killed-virus vaccines.
2. MLV vaccines generally are not adjuvanted while killed-virus vaccines are.

Bowland states that CATTLEMASTER™ BVD-K contains "cytopathic and non-cytopathic" BVDV. Applicants agree that this vaccine contains these biotypes. However, on page 36, Bowland states: "There are two biotypes of BVDV: cytopathic and non-cytopathic based on viral behavior in cell culture." Bowland also states that genotype (ie, Types 1 and 2) is unrelated to biotype (ie, cytopathic and non-cytopathic). Thus, Bowland does not teach a vaccine comprising the BVDV genotypes of types 1 and 2. Presented in Attachment 3 is a page taken from the Outline of Production for CATTLEMASTER™ BVD-K which was filed with the USDA. This clearly indicates in line 1 of paragraph D that this vaccine contains only BVDV type 1. The entire Outline of production is not included herein because much of that document contains confidential information.

The arguments previously provided regarding Barr, Pruett, and Wilson are maintained for this discussion. The Applicant respectfully submits that none of the references cited by the Examiner suggest Applicant's invention. Bowland does not teach or suggest Applicant's invention. Combining the secondary references of Barr, Pruett, and Wilson with Bowland does not make up for the deficiencies in Bowland. Even when combined the references do not yield Applicant's invention. That is, the combination of the references does not yield an immunogenic composition comprising a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI3); a modified Bovine Respiratory Syncytial Virus (BRSV); an adjuvant; a Bovine Viral Diarrhea Virus Type-1 (BVDV-1); a Bovine Viral Diarrhea Virus Type-2 (BVDV-2); and a veterinary-acceptable carrier.

Accordingly, it is respectfully submitted that the immunogenic compositions and vaccine compositions, as presently claimed, are not rendered obvious by Bowland, et al., in view of Barr, et al., Pruett, et al., and Wilson, et al. Thus, based on the remarks presented herein, when combined with the arguments provided in the responses to the prior office

actions of May 1, 2006, December 21, 2006, and April 30, 2007, the rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. 103(a) is overcome. Withdrawal of the rejection is respectfully requested.

B. The Obviousness Rejection of Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

The Examiner has rejected claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Bowland, et al., in view of Brake, et al., (US Patent No. 6,787,146, Sept 2004). Applicants respectfully traverse this rejection.

As stated above, Bowland does not teach or suggest a vaccine comprising BVDV types 1 and 2, and thus Bowland does not teach or suggest Applicant's invention. Brake describes an adjuvanted parasite homogenate vaccine. However, combining the adjuvant of the secondary reference of Brake with the compositions of Bowland does not make up for the deficiencies in Bowland because even when combined the references do not yield Applicant's invention. That is, the combination of the references does not yield an immunogenic composition comprising a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI3); a modified Bovine Respiratory Syncytial Virus (BRSV); an adjuvant; a Bovine Viral Diarrhea Virus Type-1 (BVDV-1); a Bovine Viral Diarrhea Virus Type-2 (BVDV-2); and a veterinary-acceptable carrier.

Accordingly, it is respectfully submitted that the immunogenic compositions and vaccine compositions, as presently claimed, are not rendered obvious by Bowland, et al., in view of Brake, et al. Thus, based on the remarks presented herein, the rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 under 35 U.S.C. 103(a) is overcome. Withdrawal of the rejection is respectfully requested.

III. Conclusion.

In view of the remarks made herein, Applicants respectfully submit that Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 are in condition for allowance and request notification of same.

Respectfully submitted,

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Date: January 8, 2008

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Phone No. (269) 833-2501
Fax No. (269) 833-8897

Attachment 1
(BoviShield 3)

BOVINE RHINOTRACHEITIS-VIRUS DIARRHEA-
PARAINFLUENZA$_3$ VACCINE, MODIFIED LIVE VIRUS
Product Code No. 1171.22

U. S. Veterinary License No. 189

February 27, 2007
Supersedes October 9, 2003

D. Use, Dosage and Route of Administration

This product contains Bovine Virus Diarrhea (BVD) Virus Type 1 and is recommended for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus, bovine viral diarrhea caused by bovine virus diarrhea (BVD) virus, types 1 and 2, and disease caused by bovine parainfluenza$_3$ (PI_3) virus.

Jane E. Gracier

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POLICY, EVALUATION AND LICENSING
NO ENDORSEMENT
EXPRESSED

Attachment 2.
(Bovi Shield 4)

BOVINE RHINOTRACHEITIS-VIRUS DIARRHEA-
PARAINFLUENZA$_3$-RESPIRATORY SYNCYTIAL VIRUS VACCINE
MODIFIED LIVE VIRUS
Product Code No. 1181.22

U. S. Veterinary License No. 189

February 27, 2007
Supersedes December 22, 2004

B. Collection, Storage and Submission of Representative Samples
Representative final containers shall be collected and handled in accordance with 9 CFR 113.3 (Sampling of biological products).

C. Expiration Date
The expiration date shall not exceed 24 months from the date of initiation of the first potency test. Dating has been established by data in accordance with 9 CFR 114.13 (Expiration date determination) by report titled "Real Time Stability Data to Support Expiration Dating for Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza$_3$-Respiratory Syncytial Virus Vaccine, Modified Live Virus, When Maintained Under Recommended Storage Conditions" dated April 30, 2003, approved by APHIS on October 24, 2003.

D. Use, Dosage and Route of Administration
This product contains Bovine Virus Diarrhea (BVD) Virus Type 1 and is recommended for vaccination of healthy, nonpregnant cattle as an aid in preventing infectious bovine rhinotracheitis caused by infectious bovine rhinotracheitis (IBR) virus, bovine viral diarrhea caused by bovine virus diarrhea (BVD) virus Type 1 and Type 2, and disease caused by parainfluenza$_3$ (PI$_3$) virus and bovine respiratory syncytial virus (BRSV). Bovi-Shield 4 may be administered to calves nursing pregnant cows provided their dams were vaccinated, according to label directions, with either Bovi-Shield FP 4+L5, Bovi-Shield FP 4+VL5, or PregGuard FP 9 prior to breeding.

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POLICY, EVALUATION, AND LICENSING
NO ENDORSEMENT
EXPRESSED

Attachment 3.
(CattleMaster BVD-K)

BOVINE VIRUS DIARRHEA VACCINE
KILLED VIRUS
Product Code 1205.21

U.S. Veterinary License No. 189

February 27, 2007
Supersedes September 12, 2002

B. Collection, Storage and Submission of Representative Samples
Representative final containers shall be collected and handled in accordance with 9 CFR 113.3 (Sampling of biological products). Up to 100 vials or 10 L of a pre-released serial or subserial may be shipped to Pfizer Animal Health Group, Parc Scientifique, Rue Laid Burniat No. 1, B-1348 Louvain-la-Neuve, Belgium, for concurrent testing.

C. Expiration Date
The expiration date shall not exceed 24 months from the date of initiation of the first potency test. Dating has been established in accordance with 9 CFR 114.13 (Expiration date determination), by data submitted on November 10, 1998, and filed as satisfactory by APHIS on February 26, 1999.

D. Use, Dosage, and Route of Administration
This product contains Bovine Virus Diarrhea (BVD) Virus Type 1 and is recommended for vaccination of healthy cattle, including pregnant cows, as an aid in preventing bovine viral diarrhea caused by bovine virus diarrhea (BVD) virus Type 1.

General Directions: Vaccination of healthy cattle, including pregnant cows, is recommended. Shake well. Administer 2 mL intramuscularly.

Primary Vaccination: Healthy cattle should receive 2 doses administered 2-4 weeks apart. To avoid possible maternal antibody interference with active immunization, calves vaccinated before the age of 6 months should be revaccinated after 6 months of age.

Revaccination: Annual revaccination with a single dose is recommended.

Precautions: Store at 2-7°C. Do not vaccinate within 21 days before slaughter.

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